DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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March 27, 2015

Microvention, Inc.
Ms. Naomi Gong
Sr. Regulatory Affairs Project Manager
1311 Valencia Ave
Tustin, California 92780

Re: K150366
Trade/Device Name: Sofia 6F PLUS/Distal Access Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, DQO
Dated: February 11, 2015
Received: February 12, 2015

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150366

Device Name
SOFIA PLUS/Distal Access Catheter

Indications for Use *(Describe)*
The SOFIA PLUS/Distal Access Catheters are indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Trade Name:	SOFIA™ PLUS Catheter SOFIA™ Distal Access Catheter
Generic Name:	Percutaneous Catheter
Classification:	Class II, 21 CFR 870.1250 (DQY), 21CFR 870.1200 (DQO)
Submitted By:	MicroVention, Inc 1311 Valencia Avenue Tustin, California U.S.A.
Contact:	Naomi Gong
Date:	2015 February 11
Predicate Device:	SOFIA Distal Access Catheter (K142014/K131482)

Device Description:

The SOFIA PLUS/Distal Access Catheters are a single-lumen, flexible catheter designed with coil and braid reinforcement. The distal segment is steam-shapeable and it has a hydrophilic coating for navigation through the vasculature. The radiopaque marker is located at the distal end of the catheter for visualization under fluoroscopy. An introducer sheath and shaping mandrel are also provided.

Indications For Use:

The SOFIA PLUS/Distal Access Catheters are indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.

Technological Comparison:

	SOFIA Distal Access Catheter (predicate)	**SOFIA PLUS/Distal Access Catheter**
Intended Use	Intended for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate the introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.	Same
Material Catheter Body Marker Hub Strain Relief Introducer Shaping Mandrel	 Outer layer of polyurethane elastomer (Polyblend and Pellethane), polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil, PTFE and polyolefin elastomer Platinum/Iridium Nylon Polyurethane Pebax Stainless steel	Same
Catheter size	5 F	6F
ID	0.055 inch (1.4 mm)	0.070 inch (1.78 mm)
OD	0.068 inch (1.7 mm)	0.0825 inch (2.1 mm)
Effective Length	115-125 cm	115-135 cm

	SOFIA Distal Access Catheter (predicate)	**SOFIA PLUS/Distal Access Catheter**
Coating	Hydrophilic coating (Hydak® – same)	Same
Tip Configuration	Steam shapeable by user	Same
Guidewire Compatibility	0.035 inch	Same
Accessories	Introducer sheath and shaping mandrel	Same
Method of Supply	Sterile and single use	Same
Sterilization Method	Ethylene Oxide	Same
Packaging Configuration	Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box.	Same

Verification and Test Summary:

Bench Testing		
Test	**Results**	**Conclusions**
Simulated Use	Test articles achieved a rating $\geq$ 3 for preparation/ease of assembly, introducer sheath interaction, introducer peel away, tracking with guidewire/microcatheter, microcatheter/guidewire lockup, lubricity and durability of hydrophilic coating, microcatheter/ guidewire removal, removal/ aspiration of clot, mechanical clot retriever and stent delivery with no particles	Device performs as intended under simulated use conditions
Equipment Interface	Test articles compatible with 0.035-inch guidewire, 7F or larger guide catheter/guiding sheath, common RHVs using insertion tool, stopcocks and $\leq$ 0.027-inch microcatheters	Device compatible with recommended accessories commonly used in intravascular procedures
Dimensional and Physical Attributes	Test articles met the specified dimensional requirements for catheter OD, catheter ID, overall working length, length of distal section, length of distal tip to marker band and total length of hub/strain relief	Device met established dimensional and physical specifications
Kink Resistance	No kinks at 1 cm, 4 cm, 12 cm and 25 cm from distal tip when wrapped around 0.025, 0.030, 0.040-inch pin gauges No kinks noted during simulated use testing	Device resistant to kinking around small radii turns
Tip Shapeability	Tip angle of test article equivalent to competitive devices after steam shaping using mandrel with an angle of approximately 90^{o}	Shapeability of distal tip after steam shaping – for reference
Radio Detectability	Distal marker band visible under fluoroscopy (Prior test data from predicate device)	Device radiopacity equivalent to or better than predicate and competitive devices
Gauging (ISO 594-2)	Gauging pin and hub align in limit planes (Prior test data from predicate device)	Device hub meets the requirements of ISO 594-2

Bench Testing		
Test	**Results**	**Conclusions**
Separation Force (ISO 594-2)	Mating parts separation force greater than 25 N (Prior test data from predicate device)	Device hub meets the requirements of ISO 594-2
Unscrewing Torque (ISO 594-2)	Test article luer remains attached after applying an unscrewing torque not less than 0.02 Nm for a minimum of 10 seconds (Prior test data from predicate device)	Device hub meets the requirements of ISO 594-2
Stress Cracking (ISO 594-2)	No stress cracks on test article hub (Prior test data from predicate device)	Device hub meets the requirements of ISO 594-2
Ease of Assembly (ISO 594-2)	Components fit together securely with no resistance observed between test article luer and reference fitting (Prior test data from predicate device)	Device hub meets the requirements of ISO 594-2
Resistance to Overriding (ISO 594-2)	Test article luer does not override reference fitting threads (Prior test data from predicate device)	Device hub meets the requirements of ISO 594-2
Durability/Lubricity of Hydrophilic Coating	Test article achieved a rating of $\geq$ 3 during simulated use testing for coating durability and lubricity.	Device tracks easily with no coating cracking or separation
Catheter Stiffness	Device stiffness equivalent to predicate and competitive devices	Device tracks in tortuous anatomy while advancing to target site
Torque Strength	No catheter breakage after 50 rotations	Device torque strength same as predicate device
Catheter Flexural Fatigue	No flexural fatigue following repeated bending during simulated use testing and repeated hoop stress following pressure and air aspiration testing	Device integrity suitable for intended clinical use
Surface Contamination	Test article free from surface contaminants from uncured coating surface particulates > 0.02 mm^2, embedded particulates Distal tip smooth and tapered PTFE inner layer not delaminated	Device integrity suitable for intended clinical use
Force at Break (Distal and Hub)	Catheter force at break $\geq$ 3.37 lbf for distal section and hub/catheter junction	Tensile strength test results equivalent to predicate and competitive devices
Flow Rate	Flow rate at 100 psi and 300 psi with diagnostic agents (e.g., saline, contrast media) equivalent to or better than competitive devices	Device meets specified requirements for delivery of diagnostic agents
Static Burst Pressure	No damage of pressurized catheter at 46 psi	Device integrity suitable for intended clinical use and met requirements of ISO 10555-1
Fluid Leakage at > 46 psi	No liquid leakage from hub and catheter shaft at 46 psi for 30 seconds	Device integrity suitable for intended clinical use and met requirements of ISO 10555-1
Air Leakage	No air leakage at hub into syringe for 15 seconds	Device integrity suitable for intended clinical use and met requirements of ISO 10555-1
Dynamic Burst	Test articles did not burst at or below 300 psi	Device met labeled maximum infusion pressure of 300 psi
Particulate Test	Less than 25 particles greater than 10 microns per ml volume and less than 3 particles less than 25 microns per ml volume No particles greater than 70 microns	Device met specifications for maximum allowable particles

Note: Biocompatibility was prior test data from predicate device.

Biocompatibility	Result	Conclusions
Cytotoxcitiy (ISO 10993-5) - MEM elution assay	Cell culture treated with test article exhibited slight reactivity (Grade 1)	Non-cytotoxic
Sensitization/Irritation (ISO 10993-10) - Guinea pig maximization sensitization	Extracts of the test article elicited no reaction at the challenge (0% sensitization) following the induction phase (Grade 1).	Weak allergic potential or sensitizing capacity
Sensitization/Irritation (ISO 10993-10) - Intracutaneous reactivity	Extracts of the test article did not show a significantly greater biological reaction than the sites injected with the control article	Non-irritant
Hemocompatibility – Rabbit Blood Direct and Indirect Contact (ISO 10993-4)	The hemolysis index was 0.13% (direct contact) and 0.0% (indirect contact)	Non-hemolytic
Hemocompatibility – Unactivated Partial Thromboplastin Time Assay Direct Contact (ISO 10993-4)	No statistically significant difference found between the Unactivated Partial Thromboplastin Time (UPTT) of the plasma exposed to the test article and that of the plasma exposed to either the negative control or the untreated control	No effect on coagulation
Hemocompatibility – Complement Activation Assay (ISO 10993-4)	C3a and SC5b-9 levels $\leq$ negative and untreated controls	No effect on complement activation
Hemocompatibility – Thrombogenicity Study in Dogs (ISO 10993-4)	Minimal thrombosis observed with a Grade 0 in two out of two test sites and two out of two control sites	No significant thrombosis
Systemic Toxicity – Systemic Injection Test (ISO 10993-11)	Extracts of test article did not induce a significantly greater biological reaction than the control extracts when injected in Swiss Albino mice	No toxic effects
Systemic Toxicity - Rabbit Pyrogen Test (ISO 10993-11)	The temperature increases (maximum) was 0.03^{o}C from baseline	Non-pyrogenic

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the SOFIA PLUS/Distal Access Catheter when compared with the predicate device, SOFIA Distal Access Catheter (K142014/K131482).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Are packaged and sterilized using same methods.

In summary, the SOFIA PLUS/Distal Access Catheter described in this submission is substantially equivalent to the predicate device.